

Notice of Allowability

Application No.

09/827,493

Applicant(s)

LICHTENBERGER, LENARD M.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to September 28, 2004, February 15, 2005.
2. ☒ The allowed claim(s) is/are 1-32 and 46-48 (now renumbered to claims 1-35).
3. ☒ The drawings filed on 06 April 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date hereto.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SAC 4/27/05
S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617

DETAILED ACTION

The appeal brief filed September 28, 2004 is acknowledged and has been considered.

Applicant's amendment after the appeal brief and final filed February 15, 2005 will be **entered**, since the amendment filed in order to put this application in condition for allowance, as suggested by the examiner according to the decision made by the appeal conference held February 10, 2005. See also the interview summary February 15, 2005.

Applicant's amendment filed February 15, 2005, cancels claims 33-45 directed to a nonelected invention; and amends claims 1-32 and 46-48. Currently, claims 1-32 and 46-48 are pending in this application.

Priority

As indicated in the previous Office Action, Applicant's claim for domestic priority to provisional application Serial No. 60/195,562 filed April 07, 2000 under 35 U.S.C. 119(e) is acknowledged.

Examiner's Amendment

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Robert W. Strozier on April 27, 2005.

The Claims have been amended as follows:

- Claim 15 (**currently amended**): replacing the whole claim with “A pharmaceutical composition for treating osteoporosis consisting essentially of at least one zwitterionic phospholipid and at least one bisphosphonate, and a colloidal metal, a metal complex or a mixture or combination thereof.”
 - Claim 24 (**currently amended**): replacing the whole claim with “A pharmaceutical composition for treating osteoporosis consisting essentially of a pharmaceutically effective amount of a bisphosphonate to reduce bone resorption and a sufficient amount of a zwitterionic phospholipid to reduce GI toxicity and increase the bio-availability of the bisphosphonate, and a colloidal metal, a metal complex or a mixture or combination thereof.”
- Claim 25: (**currently amended**) “A pharmaceutical composition ~~comprising a carrier and a pharmaceutically active component~~ consisting essentially of a pharmaceutically effective amount of a bisphosphonate to reduce bone resorption and a sufficient amount of a zwitterionic phospholipid to reduce GI toxicity and increase the bio-availability of the bisphosphonate, where the phospholipid is in its zwitterionic form and the bisphosphonate is in its zwitterionic form combined with a inert carrier.”
- Claim 27 (**currently amended**): replacing the whole claim with “A pharmaceutical composition consisting essentially of a pharmaceutically effective amount of a bisphosphonate to reduce bone resorption and a sufficient amount

of a zwitterionic phospholipid to reduce GI toxicity and increase the bio-availability of the bisphosphonate, and a colloidal metal, a metal complex or a mixture or combination thereof.”

Claim 30.(**currently amended**) “An oral medication for treating osteoporosis ~~comprising an solid object comprising an inert carrier and a pharmaceutical composition~~ consisting essentially of a pharmaceutically effective amount a bisphosphonate to reduce bone resorption and an amount of a zwitterionic phospholipid sufficient to reduce GI toxicity and increase the bio-availability of the bisphosphonate combined with an inert carrier and formed into a solid object.”

- Claim 32 (**currently amended**): replacing the whole claim with “An oral medication for treating osteoporosis consisting essentially of a pharmaceutically effective amount a bisphosphonate to reduce bone resorption and an amount of a zwitterionic phospholipid sufficient to reduce GI toxicity and increase the bio-availability of the bisphosphonate, and a colloidal metal, a metal complex or a mixture or combination thereof.”

Claim 48.(**currently amended**) “An oral medication for treating osteoporosis ~~comprising an solid object comprising an inert carrier and a pharmaceutical composition~~ consisting essentially of a pharmaceutically effective amount a bisphosphonate to reduce bone resorption and an amount of a zwitterionic phospholipid sufficient to reduce GI toxicity and increase the bio-availability of the bisphosphonate combined with an inert carrier and formed into a solid object, where the phospholipid is in its zwitterionic form and the bisphosphonate is in its zwitterionic form.”

Reasons For Allowance

Claims 1-32 and 46-48 are examined on the merits herein.

The claimed pharmaceutical compositions or oral medications for treating osteoporosis consisting essentially of at least one zwitterionic phospholipid and at least one bisphosphonate; or consisting essentially of a pharmaceutically effective amount a bisphosphonate to reduce bone resorption and an amount of a zwitterionic phospholipid sufficient to reduce GI toxicity and increase the bio-availability of the bisphosphonate combined with an inert carrier, are not seen to be taught or fairly suggested by the prior art, as discussed below:

Applicant's amendment submitted February 15, 2005 in the accompanying Examiner's Amendment set forth above, which limit the claims to those compositions "consisting essentially of" zwitterionic phospholipids and bisphosphonates, has been considered and is sufficient to overcome the prior art rejection made under 35 U.S.C. 103(a) as being unpatentable over DAIFOTIS, et al. (WO 9904773, of record) in view of Lichtenberger et al. (5,763,422, of record), further in view of Hovancik et al. (5,869,471, of record) of record in the previous Office Action February 26, 2004, as suggested by the examiner (see the interview summary), because all cited prior art does not teach or fairly suggest a composition consisting essentially of zwitterionic phospholipids and bisphosphonates herein; all cited prior art is not seen to provide the motivation to make a composition consisting essentially of zwitterionic phospholipids and bisphosphonates herein.

Moreover, the combined teachings of the prior art might have merely provided the motivation to add the composition of Lichtenberger et al. comprising zwitterionic phospholipids and a NSAID drug(s) to the bisphosphonate composition of Daifotis et al. for treating osteoporosis or arthritis, based on the teaching of Hovancik et al. that the combination of NSAIDs and bisphosphonates is useful in improving the therapeutic effect for treating arthritis. Hence, the combined teaching of Daifotis et al. and Lichtenberger et al. and Hovancik et al. would have suggested the combination composition comprising a bisphosphonate, a NSAID drug(s) and zwitterionic phospholipids; or at most might have provided "obvious to try" to combine zwitterionic phospholipids and bisphosphonates alone, absent a NSAID drug(s). Nonetheless, "obvious to try" is not the standard of under 103 (see MPEP 2145).

Further, Dr. Lichtenberger's second declaration with testing data submitted October 7, 2003 under 37 CFR 1.132 is seen to effectively rebut the prima facie case of obviousness herein since it is seen to provide factual evidence of nonobviousness or unexpected results for the combination of phospholipids and bisphosphonates alone.

Therefore, the cited prior art are not deemed to render the instant claimed compositions obvious to one of ordinary skill in the art. Therefore, the said rejection is withdrawn.

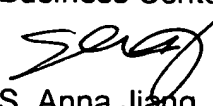
Accordingly, Applicant's amendment submitted February 15, 2005 in the accompanying Examiner's Amendment set forth above are sufficient to remove all rejections made in the prior Office Action as discussed above and place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner S. A. Jiang whose telephone number is 571.272.0627. The examiner can normally be reached on 9 am -5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
April 27, 2005